

REMARKS

In response to the outstanding final office action, applicant has made amendments to claims 1-4, 7, 9-19, 21, 24-26, 29-34, 36-43, 45-47, 58-64, 82 and 84-85. In addition, claim 44 has been withdrawn and new claims 97-99 have been added. These amendments are intended to focus the claims and to put the application in a condition for allowance. Further details regarding these amendments are outlined below.

I. The Claimed Invention

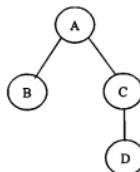
As set forth in the currently amended claims, the present invention provides a graphical user interface for assisting healthcare providers. Background for this invention is set forth in paragraph [0003] of the present application which states, “one key concern is keeping medical professionals up-to-date with new research and best practice guidelines on how to diagnose and treat conditions. At present medical best practice guidelines are arrived at by conducting a review of published research literature, going through a consensus process and evaluating any available evidence, with the guidelines being subject to review and approval by peers. The guidelines are then published and disseminated amongst practitioners. However, there is then a reliance on healthcare professionals reading and internalising the guidelines, employing them in practice as and when appropriate circumstances arise. In reality, this presents practitioners with an onerous task and many struggle to keep fully abreast of medical developments in the face of their demanding workloads, particularly general practitioners.”

The present invention provides a tool that assists a healthcare practitioner to diagnose and treat patients in accordance with the latest best practice guidelines. The graphical user interface (GUI) of the present invention presents the healthcare practitioner with a graphical representation of a map comprising a number possible patient care pathways commencing with either a suspected diagnosis or exhibited symptom. Each patient care pathway conforms with a stored best practice workflow, and is broken down into a series of nodes. The GUI is designed to guide the healthcare practitioner across the map. The guidance function helps to optimise patient care in accordance with clinical best practice guidelines, and removes the continuing burden on the

healthcare practitioner to read and internalise the latest best practice guidelines. Furthermore, the GUI provides access to up-to-date information on a particular issue as and when the practitioner is confronted with that issue.

In order to put the invention into context amendments to the claims have been made to specify the use of a GUI. For example, Claim 1 has been amended to recite “a graphical user interface (GUI) for assisting a healthcare practitioner in diagnosing and treating patients by interacting with the healthcare practitioner during progression through a stored clinical best practice workflow comprised of a plurality of interlinked steps”. Additionally, the concept of a ‘map’ has also been introduced. As an example, amended Claim 1 now conveys how the invention visually presents a series of different possible patient care pathways through the stored clinical best practice workflow, thereby enabling the healthcare practitioner to navigate the stored best practice workflow. The map is defined in amended Claim 1 as being for *“assisting the healthcare practitioner to navigate the stored clinical best practice workflow”*, and comprising *“a plurality of interlinked nodes, wherein each node has a unique relationship with a step in the stored best practice workflow”*.

It will be appreciated that, as with a geographic map, interlinking will not exist between all nodes and, as such, the map presents a series of possible pathways through the stored clinical best practice workflow to the medical practitioner. For example, on a geographic map comprising locations A, B, C and D, roads may link A to B, A to C and C to D, but there may be no road linking B to C, or B to D (see below).



Accordingly, a traveller commencing their journey at A can travel either to B, or to D via C; they cannot, however, travel from A to B and then directly to D since there is no road linking B and D. Similarly, in the presently claimed invention, whilst the map visually presents a plurality of different steps from a stored clinical best practice workflow, possible patient care pathways traversing those steps (shown by interlinking) are restricted to those permitted by the stored clinical best practice workflow. Hence, the map assists the medical practitioner to traverse a stored clinical best practice workflow, by visually presenting a series of possible patient care pathways through said workflow. This feature has been included in amended Claim 1, which now recites that "*the plurality of interlinked nodes graphically represent a plurality of possible patient care pathways across the map*".

In the amended claims, the data entry means has been expanded upon considerably. In particular, the data entry means has now been placed in context, by reciting that it is for entering "*clinical data*". Further, the data entry means comprises "*display means for displaying, within a portion of the page, a predetermined data entry request and a response made by the healthcare practitioner to the request*".

In addition to the above mentioned amendments, Claim 1 has also been amended to include "*data recording means for storing the response, made by the healthcare practitioner to the request, in a data record*", to enable the subsequently recited pathway means to be better technically described.

The pathway means itself has been revised to clarify the experience of the healthcare practitioner when interacting with the GUI. As an example, Claim 1 previously referred to the pathway means 'determining a particular pathway through the currently traversed workflow process using the entered data'. Amended Claim 1 now refers to the pathway means being "*arranged to use the response of the healthcare practitioner stored in the data record to suggest a next step within the stored best practice workflow, thereby assisting the healthcare practitioner to determine a particular patient care pathway across the map*". This amendment clarifies the fact that the healthcare practitioner ultimately decides which patient care pathway to follow, but is

assisted by the pathway means of the GUI, which suggests a route to take in the clinical best practice workflow which the healthcare practitioner may optionally elect to follow.

The suggested route is based on the data previously entered by the healthcare practitioner in response to the data request. An example of this guidance can be found in paragraph [0092], where a healthcare practitioner is advised which node to navigate to next based on the answers provided by the healthcare practitioner in response to the questions 456. The healthcare practitioner's answers trigger the GUI to issue a warning message advising the healthcare practitioner which node to navigate to next. However, the healthcare practitioner is never forced to take a suggested route through the workflow: in paragraph [0092] the healthcare practitioner is described as 'heeding' the advice and considering further information associated with the suggested node. The fact that the healthcare practitioner is never forced to follow a particular patient care pathway is of fundamental importance to the present invention; at every stage of the treatment or diagnosis, it is the healthcare practitioner that decides which pathway to follow. This feature is reflected in amended Claim 1, by the graphical means which is provided for *"graphically representing in the page a patient care pathway across the map selected by the healthcare practitioner"*.

While the features of Claim 1 have been discussed above in detail, this same theme has been continued in relation to the other independent claims. Namely, claims 45, 47, 58, 82, and 92 all contain claim language following the concepts discussed above.

II. **Claim Rejections under 35 USC §102**

In the final office action Claims 1-7, 11-16, 20-27, 35-41, 44-47, 58-64 and 82-83, were rejected under 35 USC §102 as being anticipated by Elkin et al. (hereinafter Elkin), International Publication Number WO 200171621 A1. This anticipation of rejection included each of the independent claims (namely, Claims 1, 44 to 47, 58 and 82). Applicant submits that this rejection is not appropriate, and requests allowance of the above listed claims.

Elkin is concerned with providing a GUI that "deploys predefined processes and assigns tasks for completion by employees" (page 4 lines 4-5 of Elkin). On page 5, lines 6 and 7 of Elkin,

it is described that “users log into the process server and the process server then presents them with their task assignments”. The tasks in Elkin are “fully defined” (page 4 lines 15-16). A fundamental feature of Elkin is the definition of ‘control flow’. For example, on page 9 lines 6-10 of Elkin it is described that in order to create a process model, “the control flow of the process model must be created. The control flow defines the sequence of processes and tasks in an enterprise. A user creates control flow by taking known processes and connecting the result(s) of one process to the action(s) of another process.” On page 37 line 6-7 of Elkin, it is described that the control flow is created by “wiring” together the icons on the control flow editor 340 (see Figure 14). Hence referring to Figure 14 in Elkin, the end-user performing his predefined task proceeds from one icon to the next, according to a pre-defined control flow as shown by the wiring of the icons. The results at one node determine which node the end-user progresses to next. On page 29 lines 13-16 of Elkin, the use of “flags” is described, which must be switched if the control flow is to be adjusted. The end-user in Elkin is therefore not required to navigate the workflow, but is restricted to following the predetermined pathway through the workflow, according to the predefined control flow, in which the result at one node determines which node the end-user progresses to next.

A. The Independent Claims are not anticipated by Elkin

Generally, Elkin lacks necessary teaching to anticipate several aspects of the presently claimed invention. As such, Elkin cannot anticipate the independent claims of the present application (i.e. claims 1, 46, 47, 58, 82 and 92, hereinafter “the independent claims”)¹. Elkin does not disclose a graphical user interface (GUI) for assisting a healthcare practitioner in diagnosing and treating patients as required by the independent claims. Elkin refers to administrative and business activities, and is concerned with defining business processes, as stated in the first sentence on page 1 of Elkin. There is no disclosure in Elkin that relates to healthcare or the diagnosis and treatment of patients. Further, Elkin does not describe clinical best practice workflows, patient care pathways or entering clinical data as required by the

¹ Previous independent claim 44 has been withdrawn and claim 45 has now been amended to depend from claim 1.

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independent claims.

In addition, Elkin does not disclose a “map” in the sense of the map defined in the independent claims. As recited, the map is for “assisting the healthcare practitioner to navigate the stored clinical best practice workflow”. As discussed above, the map enables the healthcare practitioner to visualise a plurality of “possible patient care pathways across the map”, thereby assisting the healthcare practitioner to navigate the stored clinical best practice workflow. There is no disclosure in Elkin of a map for assisting the end-user to navigate a workflow. Furthermore, Elkin does not disclose the graphical representation of possible patient care pathways as required in each of the independent claims. As described above, the end-user in Elkin is not required to navigate the workflow, because his route through the workflow is determined by the control flow, which is pre-defined by the process designer.

Further, Elkin does not disclose data entry means as defined in the independent claims. The data entry means allows the healthcare practitioner to “enter clinical data relating to a particular node”, and comprises “display means for displaying, within a portion of the page, a predetermined data entry request and a response made by the healthcare practitioner to the request”. The data entry request is presented to the healthcare practitioner “within a portion of the page”. As defined previously in amended Claim 1, the page also comprises the map. It is important that the data entry request is presented on the same page as the map, so that the healthcare practitioner can immediately see how the clinical data he enters may affect the patient care pathway across the map that he ultimately selects. The healthcare practitioner is progressing through the stored best practice workflow as he interacts with the GUI; he is not designing the workflow. The healthcare practitioner should therefore be compared to the end-user in Elkin, not the designer. There is no disclosure in Elkin of the end-user entering clinical data nor of the GUI displaying a predetermined data entry request to the end-user within a portion of a page comprising a map.

Elkin does not disclose a combination of data entry means, data recording means and pathway means that interact in the manner defined in the independent claims. Specifically the data entry means enables the healthcare practitioner to enter clinical data, which is stored by the data recording means, which is then used by the pathway means to *“suggest a next step within the*

stored best practice workflow, thereby assisting the healthcare practitioner to determine a particular patient care pathway across the map". As stated by the Examiner on page 3, line 10 of the Final Office Action, Elkin uses data received from the user to determine which node to process next. Whereas the amended claims makes it explicit that the healthcare practitioner ultimately determines which pathway to follow (i.e. which node to interact with next), aided by a suggestion from the pathway means which he may or may not heed, in Elkin the pathway is determined by the pre-defined control flow of the GUI. Therefore, Elkin does not disclose pathway means that suggests a next step within a stored best practice workflow, as required.

Elkin also does not disclose graphical means for representing, in the page, a patient care pathway across the map selected by the healthcare practitioner, as required by the independent claims. The Examiner argued on page 3 line 19-20 of the Final Office Action, that Figure 14 of Elkin shows a pathway that is graphically represented on the user interface. Applicant respectfully disagrees that a pathway is shown in Figure 14. As described on page 33 lines 8-16 of Elkin, "the selection panel 328 [of Figure 14] lists all repository objects available in this project", whereas the property panel [of Figure 14] displays and allows editing of the objects selected in the editor panel 330. The user interface of Figure 14 is not presented to the end-user, i.e. the person progressing through the workflow, but is rather presented to the designer. Nevertheless, the panel 328 does not show a pathway but merely a list of all objects. Further, the panel 332 does not show a pathway, merely details of the object selected in the editor panel. This is supported by the fact that panel 332 displays two alternative nodes listed consecutively, namely claim approved and claim rejected. As shown in the editor panel 330, these two nodes are not directly linked, so the end-user could not travel between them. Therefore, panel 332 cannot be showing a pathway as defined in the independent claims.

While the above comments generally apply to the independent claims, new claim 92 is worthy of additional comment. New Claim 92 is identical to Claim 1 but for the definition of the pathway means. The revised definition makes clear that the pathway means enables the healthcare practitioner to select a next step within the stored workflow rather than suggest a next

step, and thereby it assists the healthcare practitioner to determine a particular care pathway across the map.

All of the arguments made above also apply to Claim 92. More specifically Elkin does not disclose a combination of data entry means, data recording means and pathway means that interact in the way defined in amended Claim 92. New Claim 92 includes data entry means which enables the healthcare practitioner to enter clinical data, which is stored by the data recording means in a patient data record. Thus by following a particular route through the workflow the relevant data relating to a patient's condition can be obtained and stored to create a clinical history for the patient. As stated by the Examiner on page 3, line 10 of the Final Office Action, Elkin uses data received from the user to determine which node to process next. Whereas amended Claim 92 makes it explicit that the healthcare practitioner determines which pathway to follow (i.e. which node to interact with next), enabled by the pathway means which helps him to select a next step in the best practice workflow. In Elkin the pathway is determined by the pre-defined control flow of the GUI. Therefore, Elkin does not disclose pathway means that assist the user in selecting a next step in a best practice workflow as required by new Claim 92.

In view of the discussion above, it is respectfully submitted that the invention as claimed in each of the independent claims is novel over Elkin. Allowance of these claims is respectfully requested.

B. The Rejected Dependent Claims are Similarly Not Anticipated by Elkin

Each of the above comments regarding Elkin apply equally to the allegedly anticipated dependent claims. For all the same reasons, Elkin does not anticipate these dependent claims, and their allowance is respectfully requested.

With specific reference to certain amended and new claims, the novelty of each is further outlined below. More specifically, amended Claim 12 refers to at least some of the nodes including information means providing a graphical indication that concealed clinical information relating to the step in the stored best practice workflow associated with that node is available for

presentation on the page, the information means being arranged to reveal the concealed clinical information on selective interaction with the node by the healthcare practitioner. Further new Claim 87 adds the additional feature of the clinical information being revealed on the page by selection of the node itself within the GUI by the healthcare practitioner. Amended Claim 13 adds the further limitation of the graphical indication being a graphical icon. New Claim 88 adds the additional feature of the selective interaction with the node by the healthcare practitioner comprising interaction between an end-user navigational tool and the icon. New Claim 91 adds the method step of interacting with a node displaying a graphical indication that concealed clinical information relating to the step in the stored best practice workflow associated with that node is available, thereby revealing the concealed clinical information in use.

It is submitted that these amended and additional claims recite novel and advantageous features which are not disclosed in Elkin, nor in any of the other cited prior art documents. The nodes in Elkin (see for example Figures 7, 9 and 14) do not include a graphical indication that any further information is available on interaction with that node. Referring specifically to Figure 14 of Elkin, information relating to the nodes is displayed in panel 332. However, this panel is only presented to the designer, not the end-user. Claims 1 and 47 of the present application are directed to the healthcare practitioner that is progressing through the workflow, and so should be compared to the end-user in Elkin, not the designer. Elkin does not describe presenting the end-user with clinical information on interaction with a node. Furthermore, Elkin does not disclose adding a graphical indication to some of the nodes to indicate that information is available. This is a particularly advantageous feature of the present invention, because it allows the healthcare practitioner to see at a glance where further information can be obtained from, and prevents him from wasting time in interacting with nodes that do not contain further information. Moreover, by concealing information, the map can be presented on the page far more efficiently, thereby allowing the page to contain more steps of the stored clinical best practice workflow than could otherwise be displayed if all the information was presented at the same time. Further still, as the healthcare practitioner becomes more accustomed to traversing particular workflows, he may not need to read the further information at some of the nodes, and so concealing this information enables him to traverse the workflow more quickly and efficiently.

In addition to the comments above, the word “automatically” has been added to Claim 82 to further distance Claim 82 from the disclosure in Elkin. Claim 82 now includes the step of “automatically generating a graphical representation of the hierarchical clinical best practice workflow from the content recorded in the database”. Paragraph [0075] of the present application describes that the pages of the Map of Medicine as stored in the database are written in XML. These pages are then converted by the Delivery Manager into whatever format has been specified by the requesting computing device, before transmitting the pages to the browser. In contrast, the graphical representation of the workflow in Elkin is not automatically generated, but is created by the workflow designer, using the GUI (see Elkin page 35 lines 8-9: “To define a process 120, a designer 302 would first create some or all of the components 110 of the process”). Generating the graphical representation of the workflow automatically from the content recorded in the database is advantageous, because it allows a central database to be updated with the latest best practice workflows, which are then automatically represented on the screen of the healthcare practitioner as a map. As such the map seen by the healthcare practitioner is always up-to-date, contains the latest information, and displays the pathways through the workflow that conform with the latest best practice guidelines.

III. Claim Rejections under 35 USC §103

Claims 8-10, 17-19, 28-34, 42-43, and 84-86 were all rejected under 35 USC §103, based upon Elkin and various other references. Based upon the comments above, Applicant asserts that these obviousness rejections are also not valid and should be withdrawn.

In addition to the arguments regarding Elkin, Applicant submits that the combination of Elkin with Teitelbaum (U.S. Patent 6,607,482) is inappropriate for additional reasons. The Examiner refers to Teitelbaum, US 6,607,482, and notes that Teitelbaum teaches a computerized questionnaire system which takes symptoms as input and assists in making a clinical diagnosis. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the diagnosis system of Teitelbaum with the workflow system of Elkin in order to adapt the workflow system for use in the medical field. Applicants

respectfully disagree.

It is submitted that there would be no motivation for the skilled person to combine Elkin with Teitelbaum. The respective documents are directed to very different technical fields: Elkin to business processes, and Teitelbaum to medical diagnosis. Elkin does not make reference to any application in the healthcare field, and so the skilled person would not combine these documents without the use of hindsight of the present invention.

Notwithstanding the remarks above, a combination of Elkin and Teitelbaum would not result in the present invention as defined in the amended claims. This is because the GUI described in Elkin is fundamentally not suitable for assisting a healthcare practitioner in diagnosing and treating patients. As previously mentioned, it is imperative that a healthcare practitioner remains free at all times to traverse a workflow as he sees fit, without being restricted in his choice of route. Whilst the present invention assists the healthcare practitioner to navigate a workflow, by representing the workflow as a map, it does not force the healthcare practitioner along any particular pathway. In contrast, the end-user in Elkin must proceed through the workflow in accordance with the pre-defined control flow. Forcing an end-user to proceed according to a predefined control flow, as taught by Elkin, would restrict a healthcare practitioner when making a diagnosis or treating patients and prevent the healthcare practitioner drawing on his own experience or using his own judgement to pursue a different pathway through the workflow process than the one predetermined. Hence, the GUI of Elkin would *hinder* rather than assist a healthcare practitioner. It is noted that Teitelbaum merely provides a computerised questionnaire, in which a long list of questions is presented which are answered sequentially until a diagnosis is automatically arrived at. Teitelbaum does not disclose a plurality of possible patient care pathways, nor the representation of a clinical best practice workflow as a map. If Teitelbaum was combined with Elkin, the result would still be a GUI that is unsuitable for a healthcare practitioner, because the healthcare practitioner would be restricted in his traversal of the workflow process by the predefined control flow which is fundamental to the teaching of Elkin.

In light of the lack of necessary teaching in Elkin, Applicant submits that the obvious

rejections are inappropriate. As such, Applicant respectfully requests withdrawal of these rejections and allowance of these claims.

Conclusion

In light of the above amendments and arguments Applicant asserts that the present invention, as claimed, is allowable and requests favourable consideration by the Examiner.

In the event a telephone conference would expedite the prosecution of this application, the Examiner may reach the undersigned at 612-607-7387. If any additional fees are due in connection with this Amendment and Response, the Commissioner is hereby authorized to charge such fees, including extension of time fees, to Deposit Account No. 50-1901 (Ref. No. 22557-3001).

Respectfully submitted,

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